

CLAIMS

1. A pharmaceutical composition comprising 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-
5 (3-morpholinopropoxy)quinazoline or a pharmaceutically-acceptable salt thereof (the
"Agent") and a water-soluble cellulose ether or an ester of a water-soluble cellulose ether.
2. A pharmaceutical composition according to claim 1 comprising the Agent and a water-
soluble cellulose ether wherein the water-soluble cellulose ether is selected from
10 hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose and a water-
soluble salt of carboxymethylcellulose.
3. A pharmaceutical composition according to claim 1 comprising the Agent and an ester
of a water-soluble cellulose ether wherein the ester of a water-soluble cellulose ether is an
15 ester of hydroxypropyl methylcellulose or hydroxypropyl cellulose which carries one or more
ester groups selected from acetate, succinate, phthalate, isophthalate, terephthalate and
trimellitate.
4. A pharmaceutical composition according to claim 1 wherein the water-soluble
20 cellulose ether or ester of a water-soluble cellulose ether is selected from hydroxypropyl
cellulose, hydroxyethylcellulose, methylcellulose, sodium carboxymethylcellulose and
hydroxypropyl methylcellulose acetate succinate.
5. A pharmaceutical composition according to claim 1 comprising the Agent and
25 hydroxypropyl methylcellulose.
6. A pharmaceutical composition according to either claim 1 or claim 2 wherein the
water-soluble cellulose ether is not hydroxypropyl methylcellulose.
- 30 7. A pharmaceutical composition according to any one of the preceding claims wherein
the weight ratio of the Agent to water-soluble cellulose ether and ester of a water-soluble
cellulose ether is from 40:1 to 2.5:1.

8. A pharmaceutical composition according to any one of the preceding claims further comprising a wetting agent.

5 9. A pharmaceutical composition according to claim 8 wherein the wetting agent is selected from a pharmaceutically acceptable cationic or anionic surfactant.

10. A pharmaceutical composition according to claim 8 wherein the wetting agent is an alkali metal (8-20C)alkyl sulphate.

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11. A pharmaceutical composition according to any one of the preceding claims comprising the Agent, a water-soluble cellulose ether and/or ester of a water-soluble cellulose ether, a wetting agent and one or more fillers, binders, disintegrants or lubricants.

15 12. A pharmaceutical composition comprising:

(a) from 10 to 80 parts of 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically-acceptable salt thereof (the Agent);

(b) from 0.05 to 5 parts wetting agent selected from an anionic surfactant;

20 (c) from 10 to 60 parts of one or more fillers selected from lactose, mannitol and microcrystalline cellulose;

(d) from 1 to 10 parts of one or more disintegrants selected from carboxymethylcellulose sodium, carboxymethylcellulose calcium, croscarmellose sodium, crospovidone and sodium starch glycolate ;

25 (e) from 1 to 20 parts of a binder selected from a polyvinylpyrrolidone and hydroxypropyl methylcellulose; and

(f) 0 to 3 parts of a lubricant;

wherein all parts are by weight and the sum of the parts (a)+(b)+(c)+(d)+(e)+(f)=100,

and wherein at least one of the components selected from (d) or (e) contains a water-soluble

30 cellulose ether selected from hydroxypropyl methylcellulose and carboxymethylcellulose sodium.

13. A pharmaceutical composition according to any one of the preceding claims which is a solid pharmaceutical composition adapted for oral administration.

14. A solid pharmaceutical composition comprising:

- 5 (i) a core comprising 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically-acceptable salt thereof (the Agent);
and
(ii) a coating comprising an ester of a water-soluble cellulose ether or a water-soluble cellulose ether.

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15. A solid pharmaceutical composition according to claim 14 which is a tablet, pellet or granule adapted for oral administration, comprising a core coated with a film coating wherein: the core comprises:

- from 45 to 55% of the Agent;
15 from 25 to 40% lactose;
from 5 to 15% microcrystalline cellulose;
from 2 to 6% disintegrant;
from 1 to 5% povidone;
from 0.05 to 1% sodium dodecyl sulphate; and
20 from 0.1 to 4% lubricant;

and wherein the film coating comprises:

- from 0.5 to 3% water-soluble cellulose ether;
from 0 to 0.5% plasticiser;
from 0 to 0.5% dispersion aid;
25 from 0 to 0.5% opacifier; and
from 0 to 0.5% colorant;

wherein all % are by weight based upon the total weight of the composition.

16. A pharmaceutical composition according to any one of the preceding claims wherein
30 the Agent is 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline.

17. A method of preparing a pharmaceutical composition which comprises admixing 4-(3'-chloro-4'-fluoroanilino)-7-methoxy-6-(3-morpholinopropoxy)quinazoline or a pharmaceutically-acceptable salt thereof with a water-soluble cellulose ether and/or or ester of a water-soluble cellulose ether.

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18. A method for inhibiting the rate of precipitation of the Agent from solution in the GI tract of a patient in need of the Agent, comprising orally administering to said patient a composition according to any one of claims 1 to 16, wherein the Agent is as defined in claim 1.

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19. A method for reducing inter-patient variability in bioavailability and/or plasma concentrations of the Agent in a patient in need of the Agent comprising orally administering to said patient a pharmaceutical composition according to any one of claims 1 to 16, wherein the Agent is as defined in claim 1.

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20. The use of a water-soluble cellulose ether or an ester of a water-soluble cellulose ether to inhibit the precipitation of the Agent from an aqueous solution, wherein the Agent is as defined in claim 1.